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Research Article

Economic Evaluation of Sacubitril/Valsartan in Chronic Heart Failure Patients: A Markov Model Analysis in Iran

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Abstract

Background: Sacubitril/valsartan (Sac-Val) is recommended for patients with heart failure (HF) and reduced ejection fraction (HFrEF). This study aimed to evaluate the cost-effectiveness of Sac/Val in chronic HF patients in Iran.

Methods: A Markov model was constructed to assess the cost-effectiveness of Sac/Val and enalapril from a healthcare perspective over a 15-year time horizon. The primary outcome was the incremental cost-effectiveness ratio (ICER), expressed as cost per quality-adjusted life year (QALY). A discount rate of 3.5% was applied to both costs and outcomes, and a probabilistic sensitivity analysis was performed to evaluate the robustness of the results.

Results: The average costs of treating HF patients with Sac/Val and enalapril were 22,132,050,140 IRR (USD 77,442.3) and 143,043,859 IRR (USD 500.52), respectively, whereas the corresponding QALY values were 5.37 and 3.30, respectively. Sac/Val was more expensive and more effective than enalapril. The ICER was 10,635,189,214 IRR per QALY (37.06 USD/QALY), which was higher than the WHO-recommended threshold in terms of gross domestic product per capita in 2022. Sac/Val had a significant impact on increasing the QALY for HFrEF patients. At the proposed price, the cost per QALY value for Sac/Val exceeded the recommended threshold for the country.

Conclusion: Considering the country's economic context, negotiating lower prices for Sac/Val would bring it to the top of the priority list for health services.

Keywords: Cost-Utility Analysis; Markov Model; Heart Failure With Reduced Ejection Fraction; Sacubitril/Valsartan

1. Background

Heart failure (HF) presents a serious and persistent challenge to public health (1). HF is a chronic and progressive clinical syndrome caused by the functional or structural impairment of ventricles, leading to symptomatic left ventricular dysfunction. HF with a left ventricular ejection fraction of less than 40% is known as HF with reduced ejection fraction (HFrEF), or systolic HF (2). The burden of HF, which is linked to considerable morbidity, mortality, and decreased quality of life (QoL), continues to increase globally (3). Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) are the cornerstone treatment modalities for improving clinical results in patients with HFrEF. Moreover, enalapril is an ACE inhibitor (ACEi) that reduces the risk of death and hospitalization in these patients (4,5). Despite access to these therapies, the risk of death and hospitalization remains high in patients with chronic HFrEF (6). The first angiotensin receptor neprilysin inhibitor, sacubitril/valsartan (Sac/Val), is a novel combination drug used for the treatment of HFrEF (7). Angiotensin receptor neprilysin inhibitors are medicines that combine an ARB with a neprilysin inhibitor and reduce blood pressure (8). Recent clinical trials, including PARADIGM-HF, PIONEER-HF, EVALUATE-HF, and PRIME HF, have demonstrated the beneficial effects of Sac/Val in patients with HF (9-12). PARADIGM-HF demonstrated that treatment with Sac/Val, compared to enalapril, significantly reduced all-cause mortality, cardiovascular (CV) mortality, and HF hospitalization by approximately 20%. Likewise, the PIONEER-HF trial showed that, compared with enalapril, Sac/Val could considerably decrease N-terminal pro-B-type natriuretic peptide levels and HF readmissions. Current guidelines recommend the use of Sac/Val (formerly LCZ696) as the optimal drug combination in patients with HFrEF (13). HF is also a serious disease burden to the health system in Iran, and its prevalence is expected to increase with the aging population (14). In general, HF, a life-threatening condition, imposes high economic costs on society due to the need for long-term care. The highest burden of chronic HF occurs in adults aged 60 years and older (15). The complications of HF can be reduced more effectively if this disease is treated early (16). Health systems evaluate new medications to decrease the burden on secondary care, particularly inpatient costs in hospitals. Sac/Val is more expensive than an ACEi, and cost remains a major factor in easy accessibility by healthcare and patients with

HF (17-19). Accordingly, effective management of HF and reduction of its social and economic impact are priorities for healthcare in Iran. This approach requires complex treatment protocols and significant effort on the part of healthcare providers. New interventions are challenging, and comprehensive evidence can be useful for planning public health policy. As an important tool for evaluating new drugs, health economic evaluations can support the optimal allocation of limited resources. Therefore, this study aims to assess the cost-effectiveness of Sac/Val compared to enalapril in chronic HF patients with reduced ejection fraction from a healthcare perspective.

2. Materials and Methods

This economic evaluation adhered to the Consolidated Health Economic Evaluation Reporting Standards guidelines (20).

Model Structure

A Markov decision-analytic model was developed to evaluate the cost-utility of Sac/Val compared to enalapril in patients with HFrEF. In this regard, a hypothetical cohort was considered based on characteristics derived from the PARADIGM-HF trial (9). The model states were constructed based on the New York Heart Association (NYHA) function classifications I, II, III, and IV, as well as CV death and non-CV death (Figure 1). The temporary states of HF hospitalization and 30-day readmissions were included in the model. In addition, the model utilized a monthly cycle length with half-cycle correction, and the cohort population could move to the next state or remain in the current state during each cycle. The target population was advanced HF patients aged over 60 years. The analysis was performed from the perspective of the Iranian health system, and a 15-year time horizon was taken into consideration. At baseline, the simulated cohort included 60-year-old patients with HFrEF. The incremental cost-effectiveness ratio (ICER) and quality-adjusted life (QALY) were regarded as the major outcomes in this study. The threshold recommended by the World Health Organization was used in this study. Accordingly, three times the gross domestic product of Iran was considered the threshold. The costs were calculated based on 2022 Iranian rials. Furthermore, an annual discount rate of 3.5% was applied for costs and clinical outcomes beyond one year. TreeAge Pro 2018 (TreeAge Software, Williamstown, Massachusetts) was utilized to construct and analyze the model.

Model Inputs

Table 1 presents key data inputs of the model.

Transition Probabilities

Transition probabilities in the first model cycle, including the probabilities of hospitalization for HF and CV death, were obtained from the PARADIGM-HF trial (9).

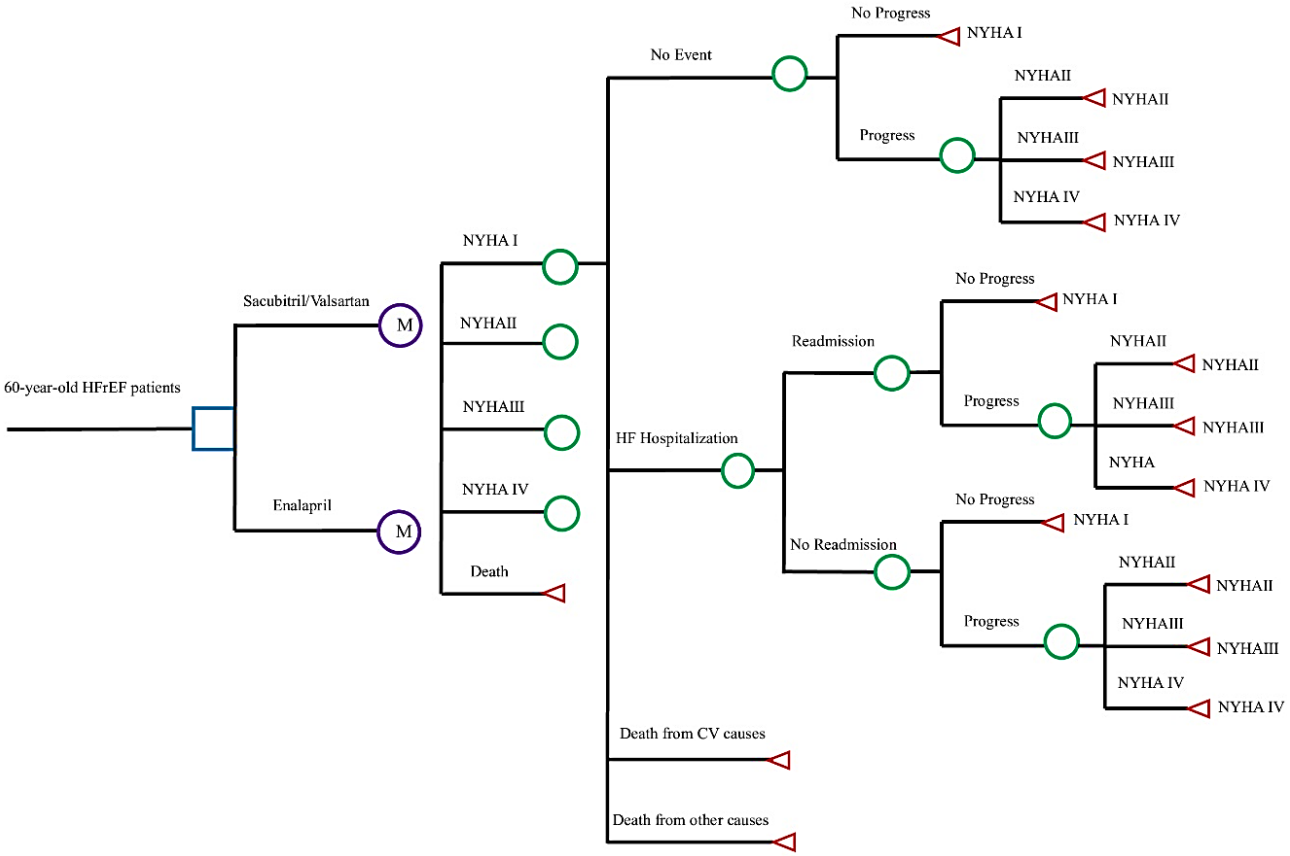

Figure 1. Structure of the Markov Decision Model. *Note*. NYHA: The New York Heart Association; CE: Cost-effectiveness; HFrEF: Heart failure and reduced ejection fraction

Table 1. Model Parameters

Variable	Base-case estimate	PSA distribution	Source
Probability of CV mortality			
Enalapril	0.006	Beta	(21)
Sacubitril/valsartan	0.005	Beta	(21)
Monthly probabilities of hospitalization			
Enalapril	0.0057	Beta	(21)
Sacubitril/valsartan	0.0047	Beta	(21)
Monthly probabilities of readmission	0.0147	Beta	(21)
Monthly probabilities of death due to causes other than CV	Iranian life tables	Table	https://apps.who.int/gho/data/view.main.60760
Utility			
NYHA class I	0.815	Beta	(22)
NYHA class II	0.720	Beta	(22)
NYHA class III	0.590	Beta	(22)
NYHA class IV	0.508	Beta	(22)
Disutility for hospitalization/readmission	−0.1	Beta	(22)
Cost			
Cost of medication (monthly)			
Enalapril	IRR 1,575,547 (USD 5.5)	Gamma	Local data
Sacubitril/valsartan	IRR 277,000,000 (USD 969.2)	Gamma	Local data
Hospitalization	IRR 62,921,498 (USD 220.16)	Gamma	Local data
Readmissions	IRR 44,045,048 (USD 154.11)	Gamma	Local data
Cost of events			
Cost of titration for sacubitril/valsartan patients	IRR 125,843 (USD 0.44)	Gamma	Local data
Elevated serum creatinine level	IRR 440,450 (USD 1.54)	Gamma	Local data
Elevated serum potassium level	IRR 566,293 (USD 1.98)	Gamma	Local data

Note. PSA: Probabilistic sensitivity analysis; CV mortality: Cardiovascular mortality; NYHA: The New York Heart Association.

In addition, the distribution of patients in the PARADIGM-HF cohort at baseline was 4.3%, 71.6%, 23.1%, and 0.8% for NYHA I, NYHA II, NYHA III, and NYHA IV, respectively. All-cause mortality in the general population was derived using age-specific and sex-specific mortality data in life tables, and the monthly probabilities of death underwent measurement. The one-month probability of transition between NYHA functional classifications was derived from an established matrix (Table 2) (21). Based on evidence from the literature, it was assumed that CV mortality remained constant throughout the model's time horizon. Patients with HF are at a considerably elevated risk of readmission after hospitalization. The probabilities of readmission for both treatment arms were considered for this study.

Table 2. NYHA Transition Probabilities per One-Month Cycle

From NYHA	to NYHA			
	Class 1	Class 2	Class 3	Class 4
Class 1	0.9923	0.0064	0.0013	0
Class 2	0.0027	0.9936	0.0034	0.0003
Class 3	0	0.0116	0.09864	0.0021
Class 4	0	0	0.0189	0.9813

Note. NYHA: The New York Heart Association.

Costs

Treatment costs, including medication costs, outpatient visits, diagnostic tests, hospitalization, and readmission, were included in this study. The monthly cost of treatment of HF patients was calculated. The medication cost was derived based on the price charged to patients for 10 mg of enalapril twice daily and 200 mg of Sac-Val twice daily. Additionally, the titration cost was taken into account for the Sac/Val group. Hospitalization and readmission costs were measured using the inpatient medical records of 522 HF patients admitted to the Madani Heart Center in Tabriz, with the assumption that the costs were similar across the two treatment groups.

Health Outcomes

Health-related QoL was obtained based on the health utility score. Furthermore, the utility values for HF health states were obtained from the published literature (22). Moreover, one-time disutilities were applied for hospitalization and readmission events (-0.1). The utility scores varied between NYHA classes (Table 2). The data indicated that NYHA class IV had the lowest utility (as

poorer QoL), whereas NYHA class I had the highest utility (as richer QoL). The utility for the death health state was set to zero.

Sensitivity Analyses

Probabilistic sensitivity analysis was performed to assess the impact of parameter uncertainty on the results of the assumptions and parameters. In addition, beta distributions were applied for transition probability and utility. Finally, gamma distributions were assumed for healthcare costs.

3. Results

Table 3 provides the results of the cost-effectiveness analysis. The findings indicated that there was a substantial difference in both impacts and costs between the two treatment strategies. The cost and effectiveness in the Sac/Val group were IRR 22,132,050,140 (USD 77,442.3) and 5.37 QALY, respectively, and the corresponding values in the enalapril group were IRR 143,043,859 (USD 500.52) and 3.30 QALY, respectively. Therefore, Sac/Val treatment was associated with higher costs and more QALY than enalapril. The ICER of the Sac/Val intervention compared with the enalapril intervention was IRR 10,635,189,214 per QALY (37.06 USD/QALY) gained, which surpassed three times the gross domestic product per capita in Iran in 2022. Figure 2 displays the results of the base case scenario.

The results of probabilistic sensitivity analyses, using cost-effectiveness acceptability, are depicted in Figures 3 ,4. The range of cost-effectiveness fluctuations was obtained by changing parameters affecting cost-effectiveness within specified distributions. The Monte Carlo simulation scatter plot illustrated that, according to the considered threshold (IRR 870,000,000 or USD 3,044.2), Sac/Val was not cost-effective compared to enalapril in 75% of the simulations.

4. Discussion

HF is considered a serious health challenge, with substantial morbidity and mortality on a global scale. The treatment of HF patients is costly; therefore, new effective products for HF management in communities are critical for improving public health. This cost-effectiveness analysis assessed Sac/Val versus enalapril for treatment in advanced HF patients 60 years and over in Iran. The results of our model indicated that while Sac/Val has a greater impact in terms of the gained QALYs, its cost is higher compared to the generics of standard therapy (e.g., ACEis) for treating patients with HFrEF. However, the corresponding ICER (IRR 10,635,189,214/QALY or 37.06 USD/QALY) suggests that Sac/Val, while effective, is not cost-effective at the proposed price compared to enalapril over a 15-year time horizon. The findings were robust to sensitivity analyses. Several studies focused on the cost-effectiveness of Sac/Val, with some controversial results. Our results confirmed the findings of four previous studies, indicating that Sac/Val at acquisition prices exceeded the cost-effectiveness thresholds in Singapore, Thailand, and the US (23-26). For instance, the incremental cost of 1 QALY gained by Sac/Val compared to enalapril in Singapore was SCD74,592 (USD 55,198). Thus, Sac/Val at proposed prices was not a cost-effective intervention for the care of HFrEF patients. The model's key drivers included the cost, CV mortality, the benefit of Sac/Val, and the time horizon (23). Krittayaphong and Permsuwan found that Sac/Val was not cost-effective compared to enalapril, with an ICER of THB 108,508 per QALY (US$3,451.26 per QALY) gained over a lifetime horizon (24). As highlighted by Earla and Sansgiry, Sac/Val was not cost-effective for reducing hospitalizations, with an ICER of $75,279 compared to enalapril, given a willingness to pay threshold of $50,000 (25). Our model results contradict numerous previous analyses, which demonstrated the cost-effectiveness of Sac/Val in patients with HFrEF as a base-case analysis or as part of a subgroup analysis. Sac/Val was a cost-effective intervention in other high-income settings, including the US (17,18,21,27), China (28), Australia (29), and the Netherlands (30), which reported the same key drivers of uncertainty in the cost-effectiveness of Sac/Val in HF. As reported by Park et al in South Korea, Sac/Val was a cost-effective treatment for patients with HFrEF. The ICER of Sac/Val versus ARBs was $11,970 over a lifetime (31). The discussed studies were conducted in different contexts, with variations in some critical parameters, making it difficult to directly compare these studies. However, all these models relied on clinical trials that had a significant impact on patient survival. The main differences among these studies, as well as methodological considerations, arise from contradictions in Sac/Val prices (the international price). The purchasing power is not similar in different countries, which will lead to different values of cost-effectiveness thresholds. To achieve equity in service utilization, the selling prices of Sac/Val should be set based on the purchasing power parity of different communities. The findings of this study revealed that the cost of Sac/Val can have a considerable effect on these outcomes. The Sac/Val is not covered by insurance funds before conducting a cost-effectiveness analysis; thus, without a context-specific discrimination of the price, the

Table 3. Base-Case Results of Cost-Effectiveness Analysis for Two Treatments

Strategy	Cost	QALY	Incremental Cost	Incremental QALY	ICER
Enalapril	IRR 143,043,859 (USD 500.52)	3,305	0	0	-
Sacubitril/valsartan	IRR 22,132,050,140 (USD 77,442.3)	5,373	IRR 21,989,006,280 (USD 76941.8)	2,076	10,635,189,214 IRR/QALY (37.06 USD/QALY)

Note. QALY: Quality-adjusted life year; ICER: Incremental cost-effectiveness ratio.

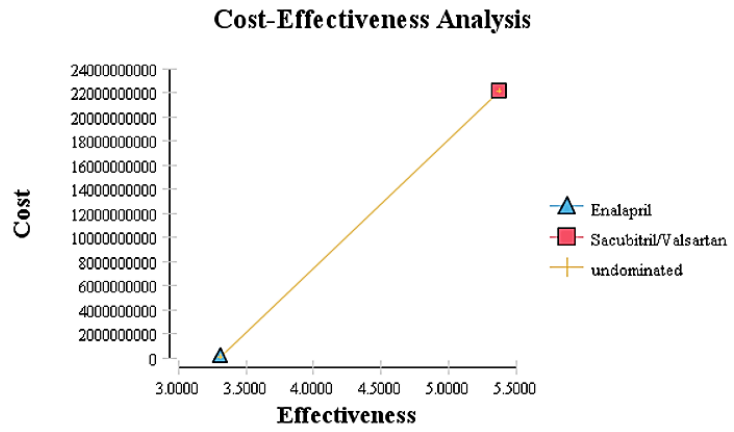

Figure 2. Cost-Effectiveness Plane From a Healthcare System Perspective

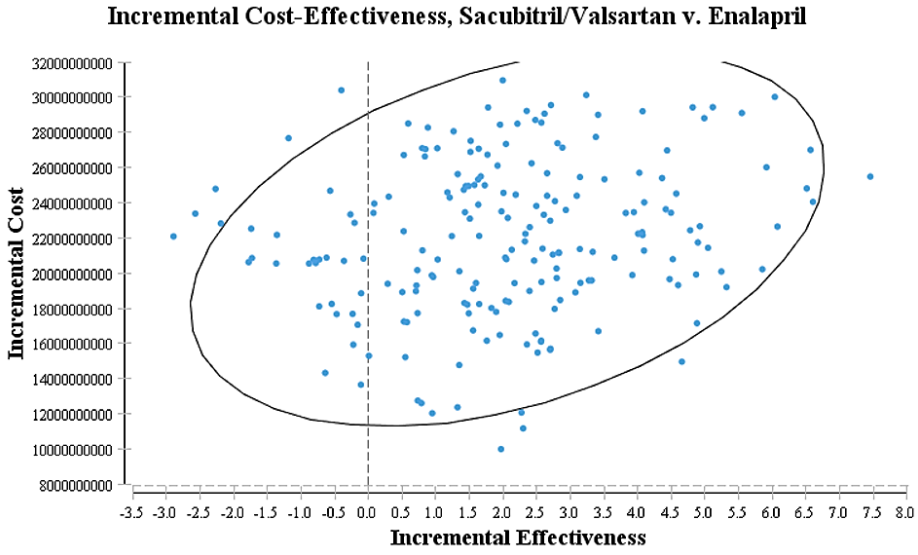

Figure 3. Incremental Cost-Effectiveness. The Results of Probabilistic Sensitivity Analysis (Monte Carlo Simulation) of Sacubitril/Valsartan Versus Enalapril

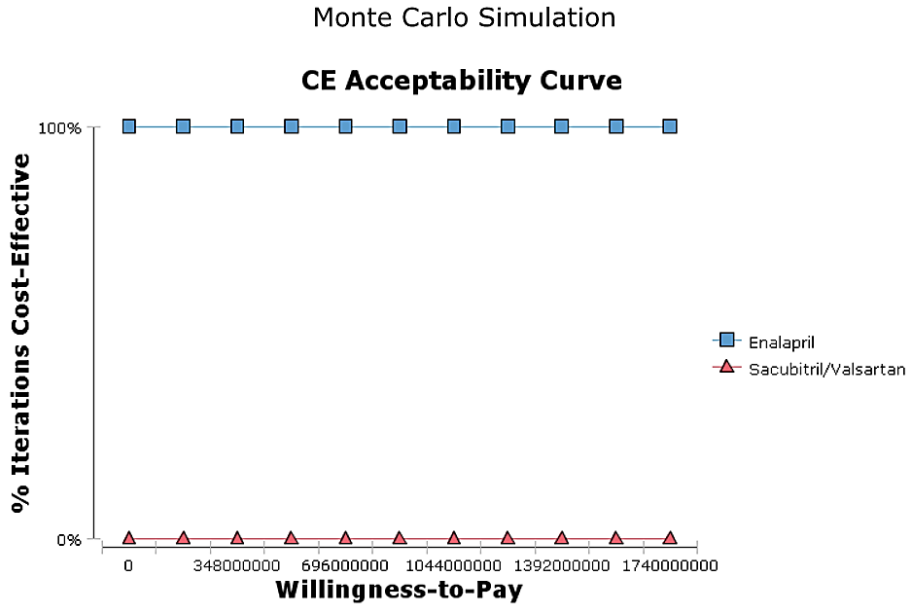

Figure 4 . Cost-Effectiveness Acceptability Curves. Note. CE: Cost-effectiveness

analysis could result in limited access to Sac/Val, leading to disparities in service financing and utilization. There is no reimbursement mechanism for this drug in Iran. However, drug costs are central to issues in the model. A change in the method of payment of expenses and under the insurance coverage of sacubitril freezing will lead to different results. Additionally, the short time horizon employed in this model affected the ICER. Similar to a study conducted in Singapore, in this study, the time horizon was considered to be short (15 years). In the study of South Korea, a time horizon of 30 years was taken into account, which could have a significant effect on the ICER.

5. Strengths and Limitations of the Study

Our study employed a comprehensive analysis to understand the costs and impacts of Sac/Val in patients with HFrEF. The model had a limitation. The utility and effectiveness relied on prior studies, limiting the generalizability of this evidence. Thus, sensitivity analyses were performed to cope with the uncertainty of the results.

6. Conclusion

The available evidence revealed that Sac/Val improves outcomes in patients with HFrEF. In conclusion, our study demonstrated that Sac/Val at proposed prices exceeds the recommended threshold of IRR 870,000,000 or USD 3,044.2. Considering the current evidence, cost remains a major barrier in the treatment of HFrEF with Sac/Val. Hence, our outcomes about the cost-effectiveness of Sac/Val substantially differ from those of most published studies, especially those conducted in high-income countries, due to the relatively higher recommended price of Sac/Val for Iran. Accordingly, our findings will help healthcare providers in medical treatment decision-making. Additionally, our analysis confirmed the critical need for more studies assessing the cost-effectiveness of Sac/Val by focusing on cost issues and insurance plans based on the Iranian population for a longer period of time.

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Authors' Contribution

Conceptualization: Maryam Chenaghlou and Mahmood Yousefi.
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Investigation: Farhad Khalili and Fatemeh Keshvari-Shad.
Methodology: Farhad Khalili and Fatemeh Keshvari-Shad.
Project administration: Maryam Chenaghlou and Mahmood Yousefi.
Resources: Mahmood Yousefi, Jebraeil Farzi, and Baharak Aghapour.
Software: Jebraeil Farzi and Baharak Aghapour.
Supervision: Maryam Chenaghlou and Mahmood Yousefi.
Validation: Mahmood Yousefi.
Visualization: Farhad Khalili and Fatemeh Keshvari-Shad.
Writing–original draft: Farhad Khalili and Fatemeh Keshvari-Shad.
Writing–review and editing: Maryam Chenaghlou and Mahmood Yousefi.

Competing Interests

The authors declare they have no competing interests.

Ethical Approval

This study was ethically approved by Tabriz University of Medical Sciences (IR.TBZMED.REC.1399.635).

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